

## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20221

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,423	10/25/2000	Masaru Kato	049441/0124	2544
75	90 01/09/2002			
Stephen A Bent Foley & Lardner 3000 K Street N W Suite 500 P O Box 25696			EXAMINER	
			RAO, MANJUNATH N	
			* 4	
Washington, Do			ART UNIT	PAPER NUMBER
			1652	
			DATE MAILED: 01/09/2002	4

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.  Og/695,423  Examiner  Manjunath N Rao  The MAILING DATE of this communication appears on the cover sheet with the correspondence address.  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Any reply received by the Office later than three months after the mailing date of this communication, earned patent term adjustment. See 37 CFR 1.704(b).  Status  1) Responsive to communication(s) filled on 25 October 2000.  2a) This action is FINAL.  2b) This action is non-final.  3) Responsive to communication for allowance except for formal matters, prosecution as to the merical closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 25-43 and 70-149 is/are pending in the application.	
Office Action Summary  Examiner  Manjunath N Rao  1652  The MAILING DATE of this communication appears on the cover sheet with the correspondence address. Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply specified above is less than thirfy (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  1) Responsive to communication(s) filled on 25 October 2000.  2a) Responsive to communication is in condition for allowance except for formal matters, prosecution as to the merical closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address.  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  1) Responsive to communication(s) filed on 25 October 2000.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the mericlosed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address.  Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply sis specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  1) □ Responsive to communication(s) filed on 25 October 2000.  2a) □ This action is FINAL.  2b) □ This action is non-final.  3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merical closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  1) □ Responsive to communication(s) filed on 25 October 2000.  - 2a) □ This action is FINAL.  - 2b) □ This action is non-final.  3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merical closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status  1) □ Responsive to communication(s) filed on 25 October 2000 .  2a) □ This action is FINAL. 2b) □ This action is non-final.  3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merical closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the mericlosed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>	ation.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the mericlosed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims	
	its is
4)⊠ Claim(s) 25-43 and 70-149 is/are pending in the application.	
,—	
4a) Of the above claim(s) is/are withdrawn from consideration.	
5) Claim(s) is/are allowed.	
6) Claim(s) is/are rejected.	
7) Claim(s) is/are objected to.	
8) Claim(s) <u>25-43 and 70-149</u> are subject to restriction and/or election requirement.	
Application Papers	
9) The specification is objected to by the Examiner.	
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.	
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).	
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.	
If approved, corrected drawings are required in reply to this Office action.  12) The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. §§ 119 and 120	
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).	
a) ☐ All b) ☐ Some * c) ☐ None of:	
1. Certified copies of the priority documents have been received.	
2. Certified copies of the priority documents have been received in Application No	
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.	
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional applic	cation).
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.	,
Attachment(s)	
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	

Application/Control Number: 09/695,423

Art Unit: 1652

## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 25-37 and 123-128, drawn to a novel amylase enzyme, classified in class 435, subclass 202.
- II. Claims 38-43, drawn to a process of producing an amylase by culturing the microorganism, classified in class 435, subclass 252.1.
- III. Claims 70-75, 90-98 and 146, drawn to a DNA fragment coding for a novel transferase, host cells and method of making the enzyme, classified in class 435 subclass 69.1.
- IV. Claim86-89, drawn to a polypeptide with transferase activity, classified in class 435, subclass 193.
- V. Claim 99, drawn to a process for producing trehalose using only transferase enzyme, classified in class 435, subclass 98.
- VI. Claims 100-122, 129-137, drawn to a DNA fragment encoding a novel amylase, host cells and method of making the enzyme, classified in class 435, subclass 69.1.
- VII. Claims 138-145, 148, 149, drawn to a process of producing alpha-alpha trehalose using amylase and transferase, classified in class 435, subclass 98.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made either by chemical synthesis or recombinant methods as opposed to the method of group II.

Inventions I, III, IV and VI are patentably distinct from each other. The polypeptides of group I and IV and the polynucleotides of group III and VI, each comprise amino acid

Application/Control Number: 09/695,423

Art Unit: 1652

sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group I polypeptide to catalyze an amylase reaction and the group IV polypeptide to catalyze a transferase reaction versus the use of polynucleotides in a hybridization reaction and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions I and V are patentably distinct from each other. The novel amylase of group I is neither used nor made in the method of group V. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the amylase enzyme can be used n a different process for example in the making of specific amylase antibodies as opposed to its use in making of trehalose.

Inventions II and III-VII are patentably distinct from each other. The method of making amylase of group II neither uses the polynucleotides of group III or VI nor the polypeptide of group IV. Furthermore, the method of group II and the methods of groups V or VII are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Invewntions III and V or VII are patentably distinct from each other. The DNA fragment of group III is neither used nor made in the methods of groups V or VII. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Application/Control Number: 09/695,423

Art Unit: 1652

Inventions IV and V or VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the transferase as claimed can be used to generate specific antibodies as opposed to its use in making of trehalose.

Inventions V and VII are patentably distinct from each other. The method of making trehalose using only transferase of group V and the method of making trehalose using both amylase and transferase is unrelated as they comprise distinct steps and utilize different products. The groups have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

A telephone call was made to Stephen Bent on 12-27-01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the

Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

Manjunath N. Rao. Ph.D. December 27, 2001